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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

June 21, 2019

Ms. Cathy Williams
Interim President and Chief Executive Officer
Reproductive Health Services of Planned Parenthood of the St Louis Region
4251 Forest Park Avenue
St Louis MO 63108

RE: RHS License Application received May 16, 2019

Ms. Williams:

The Department is in receipt of RHS's Plan of Correction (POC), dated June 18, 2019, regarding deficiencies identified in a Statement of Deficiencies (SOD) sent to your agency on June 13, 2019. The POC for the following identified deficiencies is found to be acceptable to the Department:

- Under the deficiency cited at L-1069 for failure to ensure there was communication with the pathology lab after the discovery of failed abortions, RHS's POC indicated, "RHS will notify its contracted pathology lab each time it discovers a failed abortion, even though the pathology report showed membrane/sac and/or fetal parts. RHS will incorporate this requirement into its quality assurance protocol."

- Under the deficiency cited at L-1076 for failure to ensure the physician performing the informed consent was the same physician performing the abortion, RHS's POC indicated, "If RHS continues providing care through fellows and/or residents, it will ensure that the fellow or resident provides the information required by 188.027.6 RSMo, in the presence of the attending physician, and that both the fellow or resident and the attending physician document their participation in this process. In addition, as noted in our prior plan of correction, the attending physician and the fellow and/or resident will also both be present in the procedure room. In the normal course, the fellow or resident will be the primary or sole physician providing hands-on care to the patient during the abortion procedure. However, in any instance where in the medical judgement of the attending physician the attending physician should complete the procedure, the attending physician shall do so."

- Under the deficiency cited at L-1119 for failure to ensure medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record, RHS's POC indicated, "To remedy any misunderstanding, RHS will work with its EHR system vendor to ensure that the times and dates of entries will correspond to the current time (and not the encounter date). Similarly, all documents scanned into the record will be annotated or marked with the current time and date. Because changes to the technology may take time, RHS staff will manually note the date and time and personnel in all entries until the appropriate changes can be made."

For the remaining deficiencies, however, RHS proposed no corrective actions. Of note is RHS's reversal of a previously accepted corrective action regarding the performance of pelvic examinations as part of the preoperative health assessment under 19 CSR 30-30.060(2)(D). RHS's POC, submitted on May 22, 2019, and accepted by the Department, stated that "RHS [would] revise its policies to require that a pelvic exam must be performed on the same day the patient receives the state-mandated information, at least 72 hours before the abortion." RHS's June 18, 2019 POC retracts this corrective action by stating that "unless medically indicated, we will no longer require patients seeking a surgical abortion to undergo a pelvic exam on the patient counseling day, which the State requires be at least 72 hours before the procedure."

RHS's retraction revives a practice that conflicts with current Missouri law. As the Department has previously explained, under 19 CSR 30-30.060(2)(D), the findings from a pelvic examination must be used to "detect[ ] any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management." Because the information that a pelvic examination provides could influence the choice of the procedure, a pelvic examination must occur at that time under Missouri law. Because RHS's retraction contradicts 19 CSR 30-30.060(2)(D), the POC is unacceptable under current law.

Nevertheless, the Department believes that this issue may be resolved in a manner that promotes the Department's goals of quality patient care and safety. For that reason, the Department will promulgate an Emergency Amendment and Proposed Amendment to 19 CSR 30-30.060(2)(D) that will require the physician who will perform or induce an abortion to perform a pelvic examination at least 72 hours before an abortion unless—in the clinical judgment of that physician—such pelvic examination is not medically indicated at such time for that individual patient, with such a determination being documented in detail in the patient's medical record. Thus, the Department considers the pelvic-examination deficiency, with the other deficiencies set forth above for which proposed corrective actions were accepted, as deficiencies which do not impede RHS's licensure as an abortion facility.

There remain, however, numerous additional deficiencies detailed in the SOD that RHS did not respond to with proposed corrective actions. These deficiencies are serious and extensive, including but not limited to:

- Physicians who provided patient care at RHS—including three who are still credentialed to do so—have refused to cooperate with the Department's investigation and grant interviews to the Department regarding the patient care they provided at RHS. RHS primarily defends this noncooperation by asserting that the Department had no reason to interview those physicians because the Department was allowed to interview their supervising physicians and had access to the medical records regarding that patient care. But RHS does not contend that the supervising physicians have first-hand knowledge of the events under investigation, and RHS's own medical records—which at times state that a supervising physician was "present" for a procedure that did not occur until hours later, and regarding which a later interview revealed that "present" meant that the physician was merely "available in the surgical suite"—underscore the fact interviews are necessary because medical records do not always contain all accurate information regarding the care provided. The Department is charged with safeguarding the health of the people of Missouri. For those people who receive services from a licensed facility, the Department's

ability to interview facility staff and physicians who provide patient care to determine what occurred regarding that patient care and whether corrective actions are needed is indispensable to that duty.

- RHS contends that it can take no feasible steps to compel its physicians to be interviewed, and also indicates that—even if it could take these steps—it would not do so in any event. To be clear, RHS has provided no suggestion that it encouraged or even asked the physicians providing abortions and care at its facility to cooperate in the Department's investigation. This is consistent with RHS's general stance it assumed once the Department requested interviews—that it would provide the Department solely the information regarding patient care that RHS wishes to provide and solely on its own terms. The facility's refusal to cooperate undermines the Department's ability to conduct the investigation it deems necessary to safeguard patient's health.

- A critical area of investigation that could have been explored during a requested physician interview is what precisely occurred with respect to the failed abortion of Patient #2. RHS repeats its Quality Assurance finding that the failed abortion "'most likely'" was the result of a missed twin based on documentation of fetal parts in the medical record, but RHS reaches this conclusion only by crediting the gross-examination findings and discounting another medical record—an ultrasound conducted before the failed abortion that did not reveal a twin pregnancy. (Notably, RHS also claims that the medical records include all information the Department needs for its investigation except what the attending physicians—neither of which supervised Patient #2's physician—could provide.) RHS discounts the ultrasound based on a "possib[ility]" that the patient's obesity caused the twin to be missed. As explained in the Department's cover letter to the SOD, however, the Department was forced—as a consequence of the non-cooperating physicians' refusal to submit to interviews—to presume or infer that the physicians had no satisfactory explanation for the deficiencies cited. RHS also justifies its conclusions by relying on the gross examination of fetal parts, but it is precisely the accuracy of these gross examinations that the Department cites as deficient. Only Patient #2's physician could provide the most accurate explanation for what occurred based on that physician's direct observation and treatment of the patient, and that physician has refused to be interviewed. The same is true for the failed abortion following a gross examination of fetal tissue for Patient #3, whose physician also refuses to be interviewed. Because RHS refuses to accept these grave instances as deficiencies, the Department has no assurance that such instances would not be repeated.

- RHS insists that it was "completely appropriate" to plan an abortion for Patient #12 at RHS—in fact, it provided "high-quality care" to her—despite the fact that RHS would have been completely unprepared if the severe hemorrhaging that occurred at the hospital had happened at RHS's facility. RHS does not dispute that this potential for severe hemorrhaging was a serious possibility that presented grave threat to a patient safety. And RHS provides no satisfactory explanation for the decision to disregard guidance from ACOG, which indicates that the procedure should have been performed at the hospital. Patient #12's physician has refused to be interviewed, and RHS has taken no steps to encourage him or her to do so. Our SOD thus presumes that the physician has no satisfactory explanation for the deficiency, and RHS provides no satisfactory explanation and offers no corrective action. Without acceptable corrective actions for this and the other deficiencies related to Patient #12, the Department has no reasonable

assurance that the grave harm reflected in that case would not be repeated with respect to other patients seeking abortion care.

- Regarding the informed consent required under section 188.027 RSMo for the second abortions for Patients #2 and #3, RHS alleges that it complied with this statute. But when the Department requested all consent information for these patients during its investigation on May 8, 2019, RHS provided only informed consent for the first (failed) abortions. By refusing to accept these as deficiencies, RHS consequently offers no assurance that further deficiencies will not occur.

- For Patient #1, RHS contends that an attempted surgical abortion that cannot be completed does not constitute an abortion complication (specifically a failed abortion) because the patient did not leave the facility believing her pregnancy termination was complete. In other words, RHS contends that a failed abortion is not a failed abortion so long as the patient knows the abortion failed. This explanation is not plausible and contradicts RHS's own practice of filing complication reports for failed medication abortions, where the patient also knows the abortion has failed. RHS's refusal to consider this as a deficiency likely has resulted, and will result, in fewer diagnosed abortion complications being reported, which is contrary to section 188.055.2 RSMo. In addition, the Department did not receive a complication report for Patient #1's failed medication abortion. RHS also offers no assurance that the inaccurate pelvic examination completed by a medical resident—which among other things documented the clearly pregnant patient's uterine size as less than 6 weeks—would be addressed by any plan of correction. Again, the physician fellow (who remains credentialed at RHS) and the medical resident who were present during the initial treatment of Patient #1 have refused to be interviewed, and RHS has refused to take any steps to encourage them to cooperate.

Further discussion of the RHS's responses to the numerous remaining deficiencies detailed in the SOD is not necessary. Summarily, except for those deficiencies noted at the outset of this letter, RHS fails to identify any corrective measures it will implement or identify any systemic changes it will make to ensure that the deficiencies will not recur—because RHS maintains there were no such deficiencies.

In light of the accelerated timeframe imposed by the Court—and given RHS's outright refusal to implement corrective actions with regard to such serious, extensive deficiencies as those highlighted above and those remaining in the SOD—the Department does not believe that any further progressive action regarding these deficiencies would be fruitful. Nor is such action required.

Under section 197.220 RSMo, the Department finds—based on the serious, extensive unresolved deficiencies cited in the SOD and the absence of an acceptable corrective-action plan from RHS with respect to those deficiencies—that there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240 RSMo. The Department therefore denies RHS's application for a license renewal. This denial does not preclude RHS from resubmitting an application for license at any time, provided outstanding deficiencies are resolved.

Section 197.221 RSMo contains a right of review with the Administrative Hearing Commission for a license denial:

Any person aggrieved by an official action of the department of health and senior services affecting the licensed status of a person under the provisions of sections 197.200 to 197.240, including the refusal to grant, the grant, the revocation, the suspension, or the failure to renew a license, may seek a determination thereon by the administrative hearing commission pursuant to the provisions of section 621.045 and it shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department of health and senior services.

Sincerely,

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services